

Patient Pathway for Commencing Inclisiran

Inclisiran eligibility criteria

- Adult (≥ 18 years)
- Established atherosclerotic cardiovascular disease (ASCVD), stroke, TIA, PAD and CHD
- LDL cholesterol concentrations are persistently 2.6 mmol/L or more, despite maximum tolerated lipid-lowering treatment or statin intolerant

[LSC Secondary Prevention of CVD Pathway](#)

Patient Identification

- Patients may be identified during
1. Annual QOF or LTC review
 2. Proactive computer searches such as UCLP, CDRC
 3. Pts presenting post recent ACS

Patient Consultation

Discuss treatment targets, benefits and safety and side effect profile.

Patient Declines

Document and code in notes

Patient Agrees

Book an appointment for the initial administration of inclisiran. Prescribe and order injection (via AAH)

First Appointment

1. Administer inclisiran
2. Use diary recall process for 3-month appointment
3. Prescribe and order subsequent inclisiran dose

If the planned dose is missed ≥ 3 months, start new dosing schedule

3 Month Appointment

1. Repeat lipid profile
2. Ensure reduction in LDL and relate to CHOL004
3. Check for adverse effects
4. Administer inclisiran
5. Use diary recall process for 6-month appointment
6. Prescribe and order subsequent inclisiran dose
7. Ensure patient continues on tolerated oral meds/ statin for optimum reduction in LDL

6 Monthly Maintenance Appointment

1. Repeat lipid profile annually
2. Ensure reduction in LDL and relate to CHOL004
3. Assess adverse effects
4. Administer inclisiran
5. Use diary recall process for 6-month appointment
6. Prescribe and order subsequent inclisiran dose
7. Ensure patient continues on tolerated oral meds/ statin for optimum reduction in LDL

If the patients LDL remains above **2 mmol/L** despite 9 to 12 months of inclisiran, review therapy and lifestyle interventions and seek advice and guidance from local lipid specialists

Patient Consultation

Adverse effects of inclisiran

Ordering Inclisiran and Reimbursement

Useful links

Patient Consultation

What is inclisiran and how does it work?

- Inclisiran is an injectable siRNA designed to reduce the level of LDL- cholesterol in the blood by increasing its uptake by the liver: Inclisiran is associated with a reduction in LDL of around 50% which is often observed within the first few months of therapy. One advantage of inclisiran is the six-monthly administration schedule, which may improve adherence, with reduced prescription charges for the patient (if applicable)

What are the recommendations for prescribing inclisiran in LSC?

- Inclisiran is 'Green (Restricted) as per the [LSC formulary](#) and is recommended in patients with CVD who are not reaching lipid-lowering targets despite maximal tolerated doses of high-intensity statins (e.g. atorvastatin or rosuvastatin) and if LDL is ≥ 2.6 mmol/L in line with [NICE \(TA733\)](#).

Key points to discuss with patients:

Why it's being offered

Explain their cardiovascular risk and cholesterol levels.

Clarify that inclisiran lowers LDL-cholesterol and helps reduce future cardiovascular events.

It is used when cholesterol remains high despite statins/ezetimibe, or when these are not suitable.

How inclisiran works

It helps the liver remove LDL ("bad") cholesterol by increasing LDL-receptor activity.

It is not a statin; it's an siRNA therapy.

How it is given

A **subcutaneous injection**:

Dose 1: today **Dose 2:** at **3 months** Then **every 6 months** thereafter

Can be given by a healthcare professional in clinic or at a community location

What results to expect

LDL cholesterol typically falls by **40–52%**

Cholesterol monitoring will track progress (usually at baseline, 3–4 months, and then annually unless otherwise indicated).

Common side effects

Mild injection-site reactions: redness, pain, swelling, itching, or bruising.

Usually short-lived and self-resolving.

Less common: cold-like symptoms, headache, joint aches.

Rare but important risks

Allergic reactions (rare).

Very unusual injection-site infection — seek advice if there is spreading redness, fever, or worsening pain.

What it *doesn't* do

It does **not** replace statins if statins are tolerated.

It does **not** cause muscle damage or liver toxicity in the way statins occasionally can.

What the patient needs to do

Attend scheduled injections (timing matters for effectiveness).

Maintain lifestyle measures: diet, movement, weight management, smoking cessation.

Report any unexpected or persistent symptoms

Do I stop the patients' statins if prescribing Inclisiran?

- No, Inclisiran is usually added to other current lipid lowering medications, unless they are not tolerated or there is a clinical reason to stop. Do not initiate inclisiran in patients on PCSK9 inhibitors, unless a recommendation for a therapy change comes from secondary care

Adverse effects of inclisiran

- Inclisiran is generally well tolerated, with the most common adverse effects being mild injection-site reactions such as redness, pain, swelling, or bruising. These reactions are usually short-lived and resolve without intervention.

Pregnancy and breastfeeding

- Pregnant women — there is no human data on the safety of inclisiran use during pregnancy, and animal studies do not indicate direct or indirect harmful effects. However, the manufacturer recommends avoiding it on a precautionary basis.
- Breastfeeding women — there is no human data on the safety of inclisiran use during breastfeeding, but animal studies have demonstrated its excretion in milk. Therefore, the manufacturer recommends avoiding it on a precautionary basis.

Other Precautions should be taken when prescribing to:

- People with severe hepatic or renal impairment.
- People undergoing haemodialysis — the manufacturer advises that because inclisiran is eliminated renally, haemodialysis should not be performed for at least 72 hours after inclisiran dosing.

Is inclisiran monitored under the Black Triangle Scheme?

No, the black triangle designation for inclisiran was removed late 2025 because its safety was considered sufficiently established, and no significant new safety signals had emerged with post-marketing use

Ordering Inclisiran and Reimbursement

Ordering Inclisiran

- Issued as Personally Administered Item (PAD): inclisiran as an injectable treatment, is considered a personally administered item. Practices can order inclisiran directly from the wholesaler (AAH), administer as a PA item to the patient and claim payment via the monthly submitted FP34D submission document to the NHSBSA. A prescription charge for the patient is not applicable
- To order LEQVIO®, the practice is required to have an AAH account. If you do not have an account, you can open one online at: <http://www.aah.co.uk/s/opening-an-aah-account>
- Inclisiran should be ordered directly to the GP practice (£45 per pre-filled syringe*) by calling the AAH customer care team on 0344 561 8899 or live chat with an agent via AAH Point from 9am to 5pm Monday to Friday. Same day or next delivery is available from a local AAH branch and you can order inclisiran using AAH Point or your Patient Medication Record (PMR) system using the following codes:

Product Name	EAN Code	PIP Code
Inclisiran (Leqvio®)	7613421044237	4174751

Inclisiran storage

- Inclisiran does not require any special storage conditions. It may be stored at room temperature and follow the usual process for safe and secure medicines storage at your site

Reimbursement

New NHS Commercial Agreement – Reimbursement Supplement

The new NHSE Commercial Agreement provides practices with a financial net gain of up to approximately £17.40. This comprises a £15 reimbursement supplement and an up to approx. £2.40 dispensing fee. References: <https://www.england.nhs.uk/long-read/funding-supply-inclisiran-leqvio/>

What happens when the commercial agreement finishes?

NHS England has agreed to continue to fund inclisiran centrally for all patients initiated on treatment prior to 31 December 2027. At this point, the agreement will be assessed to determine whether the current approach should continue or a revised commercial agreement is appropriate. Any revisions to the commercial agreement from 1 January 2028 will apply for new patients only. Arrangements for patients already on treatment prior to 1 January 2028 will remain in place.

Nice Guidance

[Cardiovascular disease: risk assessment and reduction, including lipid modification](#)

[Should I take a statin](#)

[TA733](#)

LSC Guidance

[LSC Lipids Primary Prevention Pathway](#)

[LSC Lipids Secondary Prevention Pathway](#)

[LSC Statin Intolerance Pathway](#)

LSC Statin Myth Busting

LSC Tackling Cholesterol Together Videos